EU Quality Management System Certificate

We hereby certify the company

Cendres+Métaux SA
Rue de Boujean 122
2501 Biel/Bienne
Switzerland

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2024-05-08	Registration No.	D1470400016
Valid until	2027-02-22	Report No.	P23-00821-271034

Stuttgart, 2024-05-08

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

EU Authorized Representative:

QualRep Services B.V.
Utrechtseweg 310 - Bldg B42,
6812 AR Arnhem, The Netherlands
NL-AR-000000537

Devices:

High-performance polymer for dental prosthesis

Risk class: IIa

Anchors Abutments

Intended purpose:
The components are intended for use in prosthetic restorations on dental implants to support procedures in the dental clinic or laboratory

Risk class: IIb

Anchors

Risk class: IIa

Slide attachments

Risk class: IIa

Bars

Intended purpose:
The male parts, which are part of prosthetic retaining elements, are fixed to at least two anchoring elements, and are intended for use in prosthetic restoration and to support procedures in the dental clinic or laboratory.

Risk class: IIb

Bars

Risk class: IIa

Root canal posts and anchors

Risk class: IIa

Dental ceramics

Risk class: IIa

Dental alloys

Risk class: IIa

Root canal instrument

Risk class: I (reusable)

Notes:

In the case of class I devices that are reusable surgical instruments the involvement of mdc is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing as well as the related instructions for use.

For the placing on the market of class III and IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors within the meaning of Regulation (EU) 2017/745, Art. 52 (4), 2nd paragraph and with the exception of custom-made devices of class III), an EU technical documentation assessment certificate is also required.

The certificate is based on the previous certificates

D1470400007 (2022-02-23)
D1470400009 (2023-01-02)
D1470400012 (2023-04-06)
D1470400015 (2024-01-18)

with the following changes to D1470400015:
Supplemented by the products:
Bars (Class IIb), Bars (Class IIa), Root canal posts and anchors, Dental alloys, Slide attachments